| | Application No. | Applicant(s) |
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| Notice of Alleman iller | 09/801,752 | SCHMIDMAIER ET AL. |
| Notice of Allowability | Examiner | Art Unit |
| · · · · · · · · · · · · · · · · · · · | Humera N. Sheikh | 1615 |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. | | |
| 1. This communication is responsive to 27 April 2005. | | |
| 2. X The allowed claim(s) is/are <u>1-6,8-30 and 60-64.</u> | | |
| 3. The drawings filed on <u>09 March 2001</u> are accepted by the Examiner. | | |
| 4. Acknowledgment is made of a claim for foreign priority una) All b) Some* c) None of the: Certified copies of the priority documents have Certified copies of the priority documents have Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)). * Certified copies not received: | e been received. e been received in Application No | |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | | |
| 5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. | | |
| 6. CORRECTED DRAWINGS (as "replacement sheets") mus (a) including changes required by the Notice of Draftspers 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Paper No./Mail Date Identifying Indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in the second sheet. | son's Patent Drawing Review(PTO s Amendment / Comment or in the C .84(c)) should be written on the drawin he header according to 37 CFR 1.121(c | Office action of ngs in the front (not the back) of d). |
| DEPOSIT OF and/or INFORMATION about the depo- attached Examiner's comment regarding REQUIREMENT | | |
| Attachment(s) | E TI Notice of the Company | |
| Notice of References Cited (PTO-892) Notice of Draftperson's Patent Drawing Review (PTO-948) | | atent Application (PTO-152) |
| | Paper No./Mail Dat | è |
| Information Disclosure Statements (PTO-1449 or PTO/SB/0 Paper No./Mail Date 07/03/01; 11/06/03 | 08), 7. ⊠ Examiner's Amendn | nent/Comment |
| 4. Examiner's Comment Regarding Requirement for Deposit | 8. 🖾 Examiner's Stateme | ent of Reasons for Allowance |
| of Biological Material | 9. | JAMES M. SPEAR PRIMARY EXAMINER |
| \cdot | • | AU 1618 |

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, Applicant's Amendment, Remarks/Arguments and the request for extension of time (1 month-granted), all filed 04/27/05 is acknowledged.

This application is in condition for allowance except for the presence of claims 32-59 drawn to an invention non-elected without traverse. Accordingly, claims 32-59 have been cancelled.

Claims 1-6, 8-30 and 60-64 are pending. Claims 1-6, 8-30 and 60-63 have been amended. Claim 31 has been cancelled (Examiner acknowledges Applicant's right to prosecute subject matter of the cancelled claim in related application(s)). Claims 32-59 have been cancelled by Examiner's Amendment. Claims 1-6, 8-30 and 60-64 are allowed.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/27/05 has been entered.

EXAMINER'S AMENDMENT

The application has been amended as follows:

In the Claims:

Claims 32-59 have been cancelled.

Allowable Subject Matter

Claims 1-6, 8-30 and 60-64 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Arm et al. WO 93/20859; Bates et al. US 6,530,951 B1; Eitenmuller et al. US 4,610,692; Healy et al. US 5,670,161) do not disclose nor fairly suggest an implant comprising a varnish-like coating having a thickness of 100 µm or less and made of a biodegradable polymer having a mean molecular weight of 100 kDa or less, wherein the varnish-like coating forms an adhesive bond to the surface of the implant. The 'varnish-like coating' of the instant invention is an improvement over prior art formulations because the varnish-like coating provides for a coating that bonds with the surface of the base material of an implant with enough adhesive strength such that, when the implant is implanted, mechanical friction will not abrade or otherwise damage the coating. It is this adhesive strength that ensures the coating is not degraded during insertion of the implant into the body. The prior art also fails to teach a varnish-like coating that is made by mixing a biodegradable polymer with an organic solvent to form a dispersion, applying the dispersion on a surface of the implant and then evaporating the organic solvent. In contrast, the prior art teaches

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prefabricated films, such as those taught by Arm et al. (WO '859), for example. The instant

implant promotes acceleration of the healing process for treating pathological changes or

conditions in the spinal column and/or locomotor system and thus demonstrates an improvement

over prior art formulations. Accordingly, the instant invention is rendered non-obvious and

patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the

payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for

Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604.

The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M.,

alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the

organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh

Patent Examiner

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June 11, 2005

JAMES M. SPEAR PRIMARY EXAMINER

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